SUPREME COURT, U.S.
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No. 843

IN THE

Supreme Court of the United States

OCTOBER TERM, 1967.

DR. F. ALLEN RUTHERFORD, ET AL.,
Petitioners,

v.

THE AMERICAN MEDICAL ASSOCIATION, INC., ET AL.,
Respondents.

ON PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT.

BRIEF FOR RESPONDENTS AMERICAN MEDICAL ASSOCIATION, INC., OLIVER FIELD, DR. ALBERT SEGALOFF, AND DR. AUSTIN SMITH, IN OPPOSITION TO CERTIORARI.

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MAY IT PLEASE THE COURT:

We respectfully submit that the petition should be denied. The judgment below is plainly correct and in accord with all relevant precedents. There is no conflict between circuits (petitioners in fact claim none); nor does the

petition present any question of special or recurring importance.[1]

I. THE DECISION BELOW IS CLEARLY CORRECT.

In essence, what the petitioners are seeking in this action is unlimited interstate distribution of an alleged "cure" for cancer—"Krebiozen"—without any compliance whatsoever with federal statutes and regulations pertaining to drugs and medicines. Petitioners are not the developers or sponsors of Krebiozen, but are instead persons who claim to be "deprived" of it because of its unavailability in commerce. During the entire 16-year controversy concerning this substance, the developers and sponsors have inexplicably refused to submit Krebiozen to the independent analysis and testing procedures of the Food and Drug Administration (FDA) established pursuant to the federal Food, Drug and Cosmetic Act (FDCA) (21 U.S.C. §355).

The FDCA delegates to the FDA primary jurisdiction to determine the safety and the effectiveness of all new drugs; the Act establishes the only procedure by which a new drug may be released in commerce for public use, either in the regular course of trade or for experimental purposes.[2] Although petitioners allege a sinister

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1. In addition, the petition plainly does not conform to the requirements of clarity and conciseness under Rule 23(4) of this Court's Rules. The 53-page petition, with its 17 "Questions Presented," fits the same description applied by the Court of Appeals to the petitioner's complaint, *i.e.*, "general, irrelevant, vituperative, scandalous and conclusory." (Petition Appendix p. 2.)

2. § 355(a) of the Act provides:

> "(a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an application filed pursuant to subsection (b) of this section is effective with respect to such drug."

Subsection (b) requires the filing of a detailed application reporting preliminary tests, composition of the substance,

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and diabolic "conspiracy" among respondents to interfere with the testing and approval of Krebiozen, they do not and cannot claim that any bona fide attempt has ever been made by Krebiozen's sponsors to comply with the regulatory procedures prescribed by Congress and the FDA. As the Court of Appeals succinctly observed:

> "Until someone has attempted to comply with the Act with respect to Krebiozen, plaintiffs' appeal should be to the sponsors of the drug." (Petition Appendix, p. 4.)

II. PETITIONERS' ARGUMENTS ARE WITHOUT MERIT.

Petitioners' contentions that the FDCA does not apply to Krebiozen are insupportable and fly in the face of the plain meaning and history of the statute. Federal regulation under the Commerce Clause is not limited to goods or articles distributed without a monetary exchange. *United States* v. *South Eastern Underwriters Ass'n*, 322 U. S. 533, 549-50 (1944); *Hipolite Egg Company* v. *United States*, 220 U. S. 45 (1911). Toxicity is not the sole criterion prescribed by the FDCA for testing new drugs; effectiveness "for use under the conditions prescribed, recommended or suggested," as well as safety, is an equally applicable consideration. *United States* v. *Allan Drug Corp.*, 357 F. 2d 713, 718 (10th Cir. 1966).

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the method and condition of manufacture and a sample of the drug itself, if requested.

If a drug is to be distributed for experimental purposes only, the sponsor may apply for an exemption from the new drug application requirements of §§ 355(a) and (b) under subsection (i) which provides:

> "(i) The Secretary shall promulgate regulations for exempting from the operation of the foregoing subsections of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs. . . ."

Equally without merit is petitioners' argument that Krebiozen is not subject to federal regulation because it is not a "drug" within the scope of the FDCA and that the mixture cannot be regulated under the Public Health Act (42 U. S. C. A. § 262). As the Court of Appeals held, there is no "gap" or "no-man's land" between the FDCA and the Public Health Act so that a substance such as Krebiozen could be freely distributed as a "cure" for cancer year after year, without any federal testing or supervision. If Krebiozen or any other alleged medicine could be dispensed to the public and represented as a cure for disease without the approval of the FDA, the entire regulatory scheme designed to protect the public safety would be seriously jeopardized, if not destroyed. This is exactly what petitioners seek under the guise of a suit for a permanent injunction.

CONCLUSION.

For the foregoing reasons we submit the petition for certiorari should be denied.

Respectfully submitted,

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